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EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 03/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/579,982

Applicant(s)

WINKLER ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-151 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 48-151 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

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1. The disclosure is objected to because of the following informalities: In the continuity data, it is stated that Serial No. 07/796243 filed November 22, 1991 is a C-I-P of Serial number 07/874849 filed April 24, 1992, but it is unclear how an earlier filed application can claim priority to a later filed application.

Appropriate correction is required.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 48-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanz in view of Meltzer.

Sanz teaches a micropipet for dispensing 1 nl of biological fluids (col. 1, lines 5-12).

Sanz fails to teach a positioning device or a polymer solution.

Meltzer teaches a positioning device for pipets for pipetting small volumes. The pipets are precisely located in the X-Y-Z dimensions (col. 1, lines 50-60) by a computer using optical, magnetic or other position detectors (col. 8, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the pipet of Sanz with the positioning device of Meltzer in order to dispense small volumes precisely into container arrays as taught by Meltzer. With respect to a source of polymer, it would have been obvious to provide a solution of DNA, RNA or proteins in order to provide a biological sample as taught by Sanz. With respect to the number of areas in the array, it would have been obvious to provide as many supports, such as microtiter trays, as required.

6. Claims 48-81, 83-91, 93-111, 113-139, 141-143, 145-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes in view of Prats.

Hayes teaches an ink jet printer for printing reagents. Droplets of 100 picoliters to 1 microliter are produced. Multiple dispensers 400 and movement between the print head(s) and substrate are used.

Hayes fails to teach positioning of the print head.

Prats teaches precise positioning of a print head in X, Y and Z directions to enhance printing (col. 1, lines 38-55) using an optical positioning system.

It would have been obvious to provide the monomers in the invention of Pirrung using an inkjet print with plural heads and relative motion means in order to provide the monomers by known means as taught by Pirrung on page 4, the known means being suitably an inkjet printer as taught by Southern and Hayes. With respect to claims limited to pipettes, it would have been obvious to use a micropipette in place of a print jet in order to deliver similar volumes as taught by Sanz. It would have been obvious to provide the dispenser spaced from the surface in order to permit drop formation and to provide means to move the dispenser relative to the substrate in order to provide art recognized equivalent to moving the substrate relative to the dispenser as taught by Prats. With respect to a source of polymer, it would have been obvious to provide a solution of DNA, RNA or proteins in order to provide biological reagents for testing as was known in the art. With respect to the number of areas in the array, it would have been obvious to provide a large plurality of spots for production of large batches of test devices.

7. Claims 48-81, 83-91, 93-111, 113-139, 141-143, 145-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung (WO/90/15070) in view of Southern (WO 89/10977) and Hayes and Prats.

Pirrung et al teach a method for forming arrays of biological polymers by coating a substrate with a protected linker, using a mask to deprotect in desired areas, adding

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an optionally protected monomer, reacting with the linker and repeating the steps to form an array (See, e.g., p. 4-7; pages 14-16, page 18 and page 28).

Pirrung fails to teach depositing by a dispenser as claimed.

Southern teaches a method similar to that of Pirrung. An ink jet printer may be used to deposit monomers (p. 11).

Hayes teaches an ink jet printer for printing reagents. Droplets of 100 picoliters to 1 microliter are produced. Multiple dispensers 400 and movement between the print head(s) and substrate are used.

Hayes fails to teach positioning of the print head.

Prats teaches precise positioning of a print head in X, Y and Z directions to enhance printing (col. 1, lines 38-55) using an optical positioning system.

It would have been obvious to provide the monomers in the invention of Pirrung using an inkjet print with plural heads and relative motion means in order to provide the monomers by known means as taught by Pirrung on page 4, the known means being suitably an inkjet printer as taught by Southern and Hayes. With respect to claims limited to pipettes, it would have been obvious to use a micropipette in place of a print jet in order to deliver similar volumes as taught by Sanz. It would have been obvious to provide the dispenser spaced from the surface in order to permit drop formation and to provide means to move the dispenser relative to the substrate in order to provide art recognized equivalent to moving the substrate relative to the dispenser as taught by Prats.

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8. Claims 82, 92, 112, 140, 144 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung in view of Sanz and Meltzer.

9. Pirrung fails to teach a pipet or plurality of pipets.

Sanz teaches a micropipet for dispensing 1 nl of biological fluids (col. 1, lines 5-12).

Meltzer teaches a positioning device for pipets for pipetting small volumes. The pipets are precisely located in the X-Y-Z dimensions (col. 1, lines 50-60) by a computer using optical, magnetic or other position detectors (col. 8, lines 1-10).

10. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the pipet of Sanz with the positioning device of Meltzer in the method of Pirrung in order to provide the monomers by known means as taught by Pirrung on page 4, the known means being dispenser(s) of small volumes precisely into arrays as taught by Sanz and Meltzer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
March 24, 2003